REMARKS

Applicants have canceled all the claims in the application without prejudice or disclaimer and have added new claims 28-35 which more particularly define the invention taking into consideration the outstanding Official Action and as fully supported by Applicants' specification as it would be interpreted by one of ordinary skill in the art to which the invention pertains taking into consideration the level of skill of one skilled in the art.

Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claims 1-27 under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims has been carefully considered but is most respectfully traversed in view of the cancellation of claims 1-27 and the replacement of these claims by a new claim set which is believed to fully comply with the requirements of 35 USC 112.

In this regard, the Examiner is most respectfully directed to MPEP § 2164.01 Test of Enablement which provides the standard for enablement. As noted therein, any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). Applying this standard it is evident that the claims are enabling to one of ordinary skill in the art without undue experimentation.

New claim 28 is original claim 1 rewritten to specify the "non-human mammal" to "livestock". As such, the specification has sufficient description to support the new claim 28 and will not create any undue experimentation.

Regarding to the purification of recombinant protein (the Examiner indicated on page 9, last paragraph), Applicants mentioned that the method to purify human clotting factor IX from transgenic swines has been disclosed in US patent application with the serial number USA 10/715,559 by Animal Technology Institute Taiwan, ATIT. Moreover, the method to purify protein may refer to the article published in Genetic Analysis: Biomolecular 1999 15:1555-160. (The description of purification of rh FIX from milk/EDTA by Van Cott et al. was shown in p157.) Furthermore, the method to purify porcine lactoferrin in the milk of transgenic swines can also refer to the literature by Chu

et al. (Am. J. Vet. Res. 1993 54:1154-1159). Accordingly, the method for purifying the recombinant proteins in this invention is well known by any person skilled in the art and will not cause undue experimentation. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1, 2, 4, 5, 6, 9, 10, 11, 14, 15, 16, 17, 18, 19, 21, 22, 23, 26 and 27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been carefully considered but is most respectfully traversed in view of the cancellation of these claims. Accordingly, it is believed that this rejection has been obviated and the withdrawal of same is most respectfully requested.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

BACON & THOMAS, PLLC

By: Richard E Fichter
Richard E. Fichter
Registration No. 26,382

625 Slaters Lane, 4th Fl.
Alexandria, Virginia 22314
Phone: (703) 683-0500
Facsimile: (703) 683-1080

REF:kdd
A01.wpd

February 7, 2005